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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,217	02/14/2002	Shai N. Gozani	NEURO-NRO-008	8764
7590	08/25/2005		EXAMINER	
Mark J. Pandiscio Pandiscio & Pandiscio 470 Totten Pond Road Waltham, MA 02154			MARMOR II, CHARLES ALAN	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 08/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/075,217	GOZANI ET AL.	
	Examiner Charles A. Marmor, II	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 31 May 2005.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-15, 18-42 and 45-62 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) 3-15, 18-38, 40-42, 45-47 and 56-62 is/are allowed.
 6) Claim(s) 1, 2, 39 and 48-55 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>05312005</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed May 31, 2005. The Examiner acknowledges the amendments to the specification and to claims 1-3, 6, 22-24, 29-31, 33-40, 48, 49 and 51-60; the cancellation of claims 16, 17, 43 and 44; and the addition of new claims 61 and 62. Claims 1-15, 18-42 and 45-62 are pending.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 39 and 48-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 39, the word "means" is preceded by the word(s) "connector" in an attempt to use a "means" clause to recite a claim element as a means for performing a specified function. However, since no function is specified by the word(s) preceding "means," it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967).

Regarding claims 48 and 55, the word "means" is preceded by the word(s) "flexible connector" in an attempt to use a "means" clause to recite a claim element as a means for performing a specified function. However, since no function is specified by the word(s)

preceding "means," it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 2 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Lemmen ('902). Lemmen discloses a sensor comprising a stimulator (14, 16) and a detector (10, 12). The stimulator (14, 16) and detector (10, 12) are connected by a connector (34, 50) and a set screw (62) such that the stimulators and detectors are capable of being automatically positioned at preselected and fixed distance (see Abstract, lines 3-5) at substantially adjacent anatomical sites. Electrical conductors are embedded within the connector. A processor is connected to the detector and is capable of selectively processing the response signals to provide a signal characteristic of the second anatomical site. The sensor is capable of assessing nerve conduction of the tibial nerve.

Allowable Subject Matter

6. Claims 3-15, 18-38, 40-42, 45-47 and 56-62 are allowable over the prior art of record.

7. Claims 48-55 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

Response to Arguments

8. Applicant's arguments filed May 31, 2005 have been fully considered but they are not persuasive. Applicant contends that Lemmen does not disclose a sensor comprising a stimulator, a detector, and connector configured to automatically position the detector substantially adjacent to a second anatomical site when the stimulator is positioned substantially adjacent to a first anatomical site inasmuch as the fixture of Lemmen is configured to adjustably position the electrodes with respect to one another. This argument is not persuasive because lines 3-5 of the Abstract of Lemmen clearly set forth that the connector allows the distance between the stimulator and the detector to be preselected and fixed. The Examiner respectfully submits that regardless of whether the fixture allows adjustable positioning of electrodes, the relative positioning is preselected and fixed such that the fixture is capable of automatically positioning the detector at a second anatomical site when the stimulator is positioned at the first anatomical site. Electrical conductors are embedded within the connector that is connected to a cord (see at least column 3, lines 63-65).

Applicant's remaining arguments, see pages 25-28 of the Remarks, filed May 31, 2005, with respect to the rejection of claims 3-5, 7-9, 23, 37, 38 and 40 under 35 USC 102(b) as being anticipated by Lemmen and the rejection of claims 1-3, 6, 7, 15, 18, 19, 22-24, 37, 38 and 48 under 35 USC 102(b) as being anticipated by Spitz et al. have been fully considered and are persuasive. The rejection of claims 3-5, 7-9, 23, 37, 38 and 40 under 35 USC 102(b) as being

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anticipated by Lemmen and the rejection of claims 1-3, 6, 7, 15, 18, 19, 22-24, 37, 38 and 48 under 35 USC 102(b) as being anticipated by Spitz et al. have been withdrawn.

Conclusion

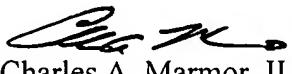
9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (571) 272-4730. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles A. Marmor, II
Primary Examiner
Art Unit 3736

cam
August 22, 2005